

LINCOMYCIN - lincomycin injection
Durvet, Inc.

LINCOMYCIN 300 INJECTION

ANADA #200-315, APPROVED BY F.D.A.

Lincomycin Injectable brand of Lincomycin hydrochloride injectable

For intramuscular Use in Swine over 300 lbs. Only

Swine Antibiotic

Lincomycin Injectable contains lincomycin hydrochloride, an antibiotic produced by *Sterptomyces lincolnensis* var. *lincolnensis*, which is chemically distinct from all other clinically available antibiotics and is isolated as a white crystalline solid.

Indicated for the treatment of arthritis caused by susceptible organisms and for mycoplasma pneumonia.

INDICATIONS FOR SWINE

Lincomycin Injectable is indicated for the treatment of infectious forms of arthritis caused by organisms sensitive to its activity. This includes most of the organisms responsible for the various infectious arthritides in swine, such as staphylococci, streptococci, *Erysipelothrix* and *Mycoplasma spp.* It is also indicated for the treatment of mycoplasma pneumonia.

CONTRAINDICATIONS

As with all drugs, the use of Lincomycin Injectable is contraindicated in animals previously found to be hypersensitive to the drug.

WARNING

Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment. **Not for human use.**

CAUTION

If no improvement is noted within 48 hours, consult a veterinarian.

ADVERSE REACTIONS

The intramuscular administration to swine may cause a transient diarrhea or loose stools. Although this effect has rarely been reported, one must be alert to the possibility that it may occur. Should this occur, it is important that the necessary steps be taken to prevent the effect of dehydration.

DOSAGE AND ADMINISTRATION

For arthritis or mycoplasma pneumonia - 5 mg per pound of body weight intramuscularly once daily for three to seven days as needed. When using Lincomycin Injectable containing 25 mg/mL, 1 mL/5 lb body weight will provide 5 mg/lb. When using Lincomycin Injectable containing 100 mg/mL, 1 mL/20 lb. body weight will provide 5 mg/lb. When using Lincomycin Injectable containing 300 mg/mL, 1 mL/50 lb. body weight will provide 5 mg/lb.

For optimal results, initiate treatment as soon as possible. As with any multi-dose vial, practice aseptic techniques in withdrawing each dose. Adequately clean and disinfect the vial closure prior to entry with a sterile needle and syringe. No vial closure should be entered more than 20 times.

HOW SUPPLIED

Lincomycin Injectable is available in three concentrations: 300 mg/mL, 100 mg/mL and 25 mg/mL.

300 mg/mL: For use in swine weighing 300 pounds or more. Each mL contains lincomycin hydrochloride equivalent to lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 mL vials.

100 mg/mL: Each mL contains lincomycin hydrochloride equivalent to lincomycin 100 mg/ also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 mL vials.

25 mg/mL: Special baby pig concentration. Each mL contains lincomycin hydrochloride equivalent to lincomycin, 25 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 mL vials.

Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 300 mg; also Benzyl Alcohol, 0.45 mg added as preservative.

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]

TAKE TIME OBSERVE LABEL DIRECTIONS.

<p>For Intramuscular Use in Swine Over 300 lbs. Restricted Drug - Use Only As Directed (California). For Use in Animals Only.</p> <p>Dosage: Usual daily dose for arthritis or mycoplasma pneumonia - 5 mg per pound of body weight (1 mL per each 60 pounds of body weight) intramuscularly for three to seven days. See package insert for complete product information.</p> <p>Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative.</p> <p>Store at controlled room temperature: 20° to 25°C (68° to 77°F) [see USP]. L-4636-04 Rev. 01-17 Lot No. Exp. Date</p> 	<p>NDC 30798-336-10</p>  <p>LINCOMYCIN 300</p> <p>300 mg/mL Sterile Lincomycin Hydrochloride Injection</p> <p>Swine Antibiotic</p>  <p>NET CONTENTS: 100 mL (3.3 fl oz)</p>	<p>Indicated for the treatment of arthritis caused by susceptible organisms and for mycoplasma pneumonia.</p> <p>Warning: Not for human use. Keep out of reach of children. Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment.</p> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p> <p>ANADA#: 200-315 Approved by F.D.A.</p> <p>Manufactured for DURVET, INC Blue Springs, Missouri 64014 www.durvet.com ISS17XB01</p> <p>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA</p> <p>OPEN HERE </p>
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<p>9.45 mg added as preservative. Supplied in 100 mL vials.</p> <p>25 mg/mL: Special baby pig concentration. Each mL contains lincomycin hydrochloride equivalent to lincomycin, 25 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 mL vials.</p> <p style="text-align: center;">7</p>	<p>Indicated for the treatment of arthritis caused by susceptible organisms and for mycoplasma pneumonia.</p> <p>Warning: Not for human use. Keep out of reach of children. Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment.</p> <p style="text-align: center;">  TAKE TIME OBSERVE LABEL DIRECTIONS </p> <p>ANADA#: 200-315 Approved by F.D.A.</p> <p> <small>Manufactured for</small> DURVET, INC <small>Blue Springs, Missouri 64014</small> <small>www.durvet.com</small> <small>ISS17XB01</small> </p> <p> <small>Manufactured by</small> Sparhawk Laboratories, Inc. <small>Lenexa, KS 66215, USA</small> </p>	<p>Lincomycin Injectable brand of Lincomycin hydrochloride injectable For Intramuscular Use in Swine Only</p> <p>Lincomycin Injectable contains lincomycin hydrochloride, an antibiotic produced by <i>Streptomyces lincolnensis var. lincolnensis</i>, which is chemically distinct from all other clinically available antibiotics and is isolated as a white crystalline solid.</p> <p>INDICATIONS FOR SWINE Lincomycin Injectable is indicated for the treatment of infectious forms of arthritis caused by organisms sensitive to its activity.</p> <p style="text-align: center;">1</p>	<p>This includes most of the organisms responsible for the various infectious arthritides in swine, such as staphylococci, streptococci, <i>Erysipelothrix</i> and <i>Mycoplasma</i> spp. It is also indicated for the treatment of mycoplasma pneumonia.</p> <p>CONTRAINDICATIONS As with all drugs, the use of Lincomycin Injectable is contraindicated in animals previously found to be hypersensitive to the drug.</p> <p style="text-align: center;">2</p>
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<p>WARNING Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment. Not for human use.</p> <p>CAUTION If no improvement is noted within 48 hours, consult a veterinarian.</p> <p>ADVERSE REACTIONS The intramuscular administration to swine may cause a transient diarrhea or loose stools. Although this effect has rarely been reported, one must be alert</p> <p style="text-align: center;">3</p>	<p>to the possibility that it may occur. Should this occur, it is important that the necessary steps be taken to prevent the effects of dehydration.</p> <p>DOSAGE AND ADMINISTRATION For arthritis or mycoplasma pneumonia - 5mg per pound of body weight intramuscularly once daily for three to seven days as needed. When using Lincomycin Injectable containing 25 mg/mL, 1 mL/5 lb. body weight will provide 5 mg/lb. When using Lincomycin Injectable</p> <p style="text-align: center;">4</p>	<p>containing 100 mg/mL, 1 mL/20 lb. body weight will provide 5 mg/lb. When using Lincomycin Injectable containing 300 mg/mL, 1 mL/60 lb. body weight will provide 5 mg/lb. For optimal results, initiate treatment as soon as possible. As with any multi-dose vial, practice aseptic techniques in withdrawing each dose. Adequately clean and disinfect the vial closure prior to entry with a sterile needle and syringe. No vial closure should be entered more than 20 times.</p> <p style="text-align: center;">5</p>	<p>HOW SUPPLIED Lincomycin Injectable is available in three concentrations: 300 mg/mL, 100 mg/mL, and 25 mg/mL.</p> <p>300 mg/mL: For use in swine weighing 300 pounds or more. Each mL contains lincomycin hydrochloride equivalent to lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 mL vials.</p> <p>100 mg/mL: Each mL contains lincomycin hydrochloride equivalent to lincomycin 100 mg; also Benzyl Alcohol,</p> <p style="text-align: center;">6</p>
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LINCOMYCIN				
lincomycin injection				
Product Information				
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:30798-336	
Route of Administration	INTRAMUSCULAR			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
LINCOMYCIN HYDROCHLORIDE (UNII: M6T05Z2B68) (LINCOMYCIN - UNII:BOD072YW0F)		LINCOMYCIN	300 mg in 1 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30798-336-10	100 mL in 1 VIAL		
Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Category	Citation	Date	Date
ANADA	ANADA200315	06/03/2003	

Labeler - Durvet, Inc. (056387798)

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Durvet, Inc.